

**Notice of Allowability**

Application No.

09/994,185

Examiner

Karen A. Canella

Applicant(s)

WHITE ET AL.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed July 29, 2005.
2. ☒ The allowed claim(s) is/are 1-4, 6-18, renumbered as 1-17, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

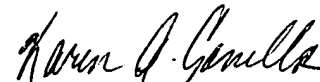
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Li-Hsien Rin-Laures on November 21, 2005.

The application has been amended as follows:

Claim 1 has been replaced with the following:

1. A method for specifically determining exposure of a subject to endotoxin comprising the steps of  
determining the concentration of lipopolysaccharide binding protein (LBP) in a sample of body fluid from the subject, and  
correlating the concentration of LBP with a standard indicative of the exposure to endotoxin,  
wherein LBP concentration above the standard is presumptively diagnostic of exposure of the subject to endotoxin, while a concentration below the standard is not, and  
wherein said subject has a pathological condition which is not a gram-negative bacterial infection or wherein said subject has a pathological condition in addition to a gram-negative bacterial infection.

Claim 18 has been added:

18. A method for specifically determining exposure of a subject to endotoxin comprising the steps of  
determining the concentration of lipopolysaccharide binding protein (LBP) in a sample of body fluid from the subject, and  
correlating the concentration of LBP with a standard indicative of the exposure to endotoxin,

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wherein LBP concentration above the standard is presumptively diagnostic of exposure of the subject to endotoxin, while a concentration below the standard is not, and

wherein said subject is pregnant.

Claim 5 has been canceled.

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance: the instant method is novel and unobvious over the prior art. The recitation of "said subject not known to be suffering from a gram-negative bacterial infection" finds support in the specification on page 13, lines 21-29 wherein it is contemplated that the LBP assay of the invention is valuable for distinguishing conditions associated with endotoxin from other acute phase conditions or non-acute phase conditions not associated with endotoxin in patients having acute lymphoblastic or chronic lymphocytic leukemia, cutaneous T-cell lymphoma, type 1 diabetes, aplastic anemia, Crohn's disease, psoriasis, rheumatoid arthritis, scleroderma, systemic lupus erythematosus, AIDS, graft versus host disease and pregnancy. Support for "gram-negative bacterial infection" can be found on page 14, lines 27-29, wherein it is contemplated that LBP levels can be determined in plasma taken from suspected gram-negative sepsis patients, as well as the general knowledge in the art that LPS is an endotoxin which is produced by gram-negative bacteria.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

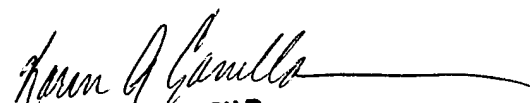
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

11/28/2005

  
KAREN A. CANELLA, PH.D.  
PRIMARY EXAMINER